

### **REMARKS**

Claim 12 has been rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Additionally, claim 11 has been rejected as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claims 1-16 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,331,158 to Hu (“Hu”). The Examiner asserts Hu discloses all the features of Applicants’ claims. As a result of the above amendments, Claims 1-16 have been cancelled and Claims 17-31 have been newly added. No new matter has been added. In view of the new claims presented herein, Applicants respectfully traverse these rejections.

#### **Rejection Under 35 U.S.C. §102(e)**

The Examiner rejected claims 1-16 under 35 U.S.C. §102(e) as being anticipated by Hu. The Examiner asserts Hu discloses all the features of these claims. In light of newly amended claims 17-31 presented herein, Applicants respectfully traverse these rejections.

First, Applicants respectfully disagree with the Examiner’s description of the disclosure of Hu, as such Applicants submit an accurate and detailed summary of the disclosure of Hu. Specifically, Hu discloses a “surgical retractor, instrument mount, and tissue stabilizer device for use during coronary artery bypass surgery” that includes a “retractor assembly 10, mount assembly 20 and stabilizer assembly 30.” (Col. 1, lines 7-9; Col. 7, lines 35-36; FIG. 1). The retractor assembly 10 includes “a pair of opposing blades adapted to engage opposite sides of a sternal incision, or other incision, and a drive mechanism constructed to force the blades, and thus the sternum apart.” (Col. 7, lines 37-40). “The retractor assembly 10 comprises a drive 12 and first and second platform blades 14 and 16 detachably connected to drive 12, as illustrated in FIG. 2. Preferably first platform blade 14 and second platform blade 16 each have one or more channels or engaging members 18 adapted to engage opposite sides of an access incision. Activation of drive 12 forces apart first and second platform blades 14 and 16 thereby causing engaging members 18 to force open the incision.” (Col. 9, lines 12-21). Thus, Hu, when the target vessel is in a desired position, “at least one component of the stabilizer assembly 30 is brought into contact with the beating heart adjacent the target site of anastomosis” and the

stabilizer is fixed in place preferably to “the retractor assembly 10 by way of mount assembly 20.” (Col. 7, lines 51-54; Col. 7, lines 55-57).

In order for a reference to act as a § 102 bar to patentability, the reference must teach each and every element of the claimed invention. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Applicants respectfully submit Hu does not disclose each and every element of any independent claim, and as such the claims are not anticipated by Hu. Further, as explained below, the invention of Hu is provided to solve an entirely different problem related to accessing, positioning, and stabilizing the beating heart for coronary artery bypass graft surgery. The structure and function of Hu is extremely different from Applicants’ amended claims, and as such Hu also does not render any of the claims anticipated.

#### **Independent Claim 17**

Unlike Hu, amended independent claim 17 recites: “a clamp having an opening for receiving a portion of the arm, and a latch connected to the clamp for selectively retaining the clamp at a selected position on the arm; an angularly adjustable leg pivotally coupled to the clamp, the leg having a mount for receiving a connector head of a retractor blade; and, an operator connected to the leg to adjust the angular position of the leg with respect to the clamp.”

Such recitation is not disclosed in Hu, and rather Applicants’ invention is very different from the structure and operation of Hu. Specifically, Hu requires a “retractor assembly 10, mount assembly 20 and a stabilizer assembly 30.” (Col. 1, lines 7-9; Col. 7, lines 35-36; FIG. 1). As discussed in greater detail above, the retractor assembly 10 of Hu has a set of blades that engage a sternum and force it apart in order to keep the chest cavity open during surgery. The retractor assembly 10 has a mount assembly 20 that receives a stabilizer assembly 30. The stabilizer assembly 30 fixes the heart in place, out of the patient’s chest cavity, so that a surgeon can accurately and effectively perform the required procedure. Accordingly, the Hu reference does not have “a clamp having an opening for receiving a portion of the arm.” The Examiner states that Hu discloses a retractor clamp 20 capable of being engaged on the second arm. More specifically, The Examiner cites to column 8, lines 40-47 of Hu for support of such disclosure. Column 8, lines 40-47 of Hu discloses the following:

“In one embodiment, the blades may be permanently, integrally, or inseparably formed with the drive mechanism. Preferably however, at least a portion of the blades are separable from the drive mechanism. That is, at least

some of the features and functions associated with the retractor blades are allocated to a structural component which is separate, separable, or otherwise detachable from the drive mechanism.”

Based on the above, Applicants respectfully submit the Examiner has failed to identify in Hu “a clamp having an opening for receiving a portion of the arm.” Furthermore, The Examiner states Hu discloses a retractor clamp 20, when in fact Hu discloses a mount assembly 20, not a retractor clamp. Applicants submit the mount assembly 20 of Hu is not a retractor clamp as defined in Applicants’ claims. Additionally, The Examiner has failed to identify a clamp of Hu having an opening for receiving an arm portion, as required by Applicants’ invention. Rather, the mount assembly 20 of Hu “may be positioned at a desired location along an appropriate rail and secured by rail grips 114 and 116.” (Col. 16, lines 39-41). Unlike Applicants’ invention, Hu utilizes rail grips 114 and 116 to secure the mount base on a rail, whereas Applicants’ invention requires the clamp to have an opening for receiving an arm portion.

Claim 17 as amended further requires a “latch connected to the clamp for selectively retaining the clamp in a selected position on the arm.” The Examiner asserts that Hu discloses element 116 that is connected to the member for selectively retaining the latch. As mentioned above, 116 refers to one of the rail grips 116 in Hu, not a latch as required by Applicants’ invention. The rail grips are provided in Hu to grip mounting tabs and not an arm.

Additionally, Applicants respectfully submit that Hu fails to disclose “an angularly adjustable leg pivotally coupled to the clamp” as required by amended Claim 17. The Examiner has identified element 140 as the leg required by claim 17. However, The Examiner’s identification of the alleged leg 140 in Hu is actually a shaft grip 140. Hu discloses a shaft grip 140 that receives upper and lower shaft locks 136 and 137 to form a shaft assembly 160. (Col. 19, lines 3-5). Hu further discloses that “[a]s clutch member 135 is received over the outside diameter of grip housing 141 of shaft grip 140 tang 164 becomes engaged between upper shaft lock 136 and lower shaft lock 137 thereby preventing relative rotation between clutch member 135 and shaft grip 140. (Col. 19, lines 7-11). Unlike Applicants’ invention which requires the leg to be “angularly adjustable” and “pivotally coupled to the clamp,” Hu’s shaft grip 140 cannot function as such. In fact, Hu discloses that “translation and rotation of instrument shaft 3 is *prevented* as shaft grip 140 and clutch member 135 are forced together to clamp or trap instrument shaft 3 between shaft locks 136 and 137 and outer shaft guide 144.” (Col. 19, lines

17-21). Because of this, Applicants represent Hu actually teaches away from this structure and thus the shaft grip 140 of Hu cannot be construed to anticipate Applicants' invention that requires an angularly adjustable leg pivotally couple to the clamp.

Finally, Applicants' amended independent claim 17 requires "an operator connected to the leg to adjust the angular position of the leg with respect to the clamp." Applicants respectfully disagree with The Examiner's assertion that Hu discloses a threaded adjustment mechanism 119 that anticipates Applicants' operator. Hu discloses

"[s]ide mount knob 118 having a threaded shaft 119 extends through mount body 110 (and consequently through transverse bore 131 in central portion 167 of base post 130), clutch member 135 and into interior threads 142 within grip housing 141 of shaft grip 140. Tightening of the side mount knob 118 clamps the assembly together. Thus translation and rotation of the instrument is prevented as shaft grip 140 and clutch member 135 are forced together....(Col. 19, lines 12-19).

The disclosure in Hu is unlike the operator of Applicants' invention. Unlike The Examiner's assertions, the threaded shaft 119 of Hu, is used to tighten, or screw, a portion of Hu's apparatus together to prevent the parts from coming loose. Hu's threaded shaft 119 actually **prevents** components of Hu from moving, whereas the operator of Applicants' invention adjusts the angular position of the leg with respect to the clamp. Consequently, the threaded shaft 119 of Hu cannot be construed to anticipate Applicants' operator that requires being able to angularly adjust the position of the leg with respect to the clamp.

Since Hu does not disclose each and every element of independent claim 17, Hu does not anticipate claim 17. Thus Applicants respectfully assert claim 1 and all dependent claims thereon are patentable as amended.

### **Independent Claim 29**

In addition to the limitations discussed above for newly amended independent claim 17, claim 29 further requires as part of its surgical retractor a clamp comprising, "a member having a slot for receiving a portion of the arm therethrough. . . ."

Applicants respectfully disagree with The Examiner's contention that Hu discloses a slot as required by Applicants' invention. The Examiner indicates that Hu discloses a slot on FIG. 14 as defined by reference number 125. Applicants contend that reference numeral 125 of Hu refers to the mount base 125, not a slot. The mount base 125 is secured onto a rail utilizing rail grips

114 and 116, which have hook-like features, to engage the rail, rather than a slot as required by Applicants' invention. Thus, the Examiner has failed to adequately identify a slot in the mount base 125 of Hu.

Additionally, Applicants respectfully submits that Hu fails to disclose "a leg pivotally connected to the clamp and extending cantilevered therefrom" as required by amended Claim 29. The Examiner states Hu discloses shaft grip 140, which allegedly as anticipates the leg required by Applicants' invention. The shaft grip 140 of Hu, however, is not pivotally connected to the clamp, nor does it extend cantilevered therefrom. Instead, as discussed above, the shaft grip 140 of Hu is secured to the shaft hub assembly 160 and is meant to securely anchor the instrument shaft 3 to prevent translation and rotation. (Col. 19, lines 17-21). Accordingly, the shaft grip 140 of Hu is not capable of being pivotally connected to the clamp because it is intended to hold the instrument 3 in place. Furthermore, the shaft grip 140 does not extend cantilevered from the clamp. As shown in FIG. 14, the shaft grip 140 resembles a cylindrical tube-like structure having no corresponding structure that could be construed as being a cantilevered structure.

Applicants further contend Hu fails to disclose a "latch connected to the clamp for selectively retaining the clamp in a selected position on the arm"; "an angularly adjustable leg pivotally coupled to the clamp;" and "an operator connected to the leg to adjust the angular position of the leg with respect to the clamp" for the same reasons discussed above. As such, Hu does not disclose each and every element of independent claim 29 as newly amended, and thus Hu does not anticipate claim 29. Applicants respectfully assert claim 29 and all dependent claims thereon are patentable as amended.

### **Independent Claim 30**

In addition to the limitations discussed above for newly amended independent claims 17 and 29, claim 30 further requires as part of its surgical retractor a clamp comprising, "a slot defined by an upper surface and a lower surface."

As explained above, the Examiner asserts Hu discloses a slot on FIG. 14 as defined by reference number 125. Applicants respectfully submit the element in Hu bearing reference numeral 125 refer to the mount base 125, not a slot. Unlike the slot of Applicants' invention, the mount base 125 of Hu has rail grips 114 and 116, with hook-like structures to secure onto a rail. In contrast, claim 30 as amended requires a slot defined by an upper and lower surface, in which

the slot resembles a C-like shape. The mount base 125, even if viewed in connection with the rail grips 114 and 116 does not disclose a slot defined by an upper and lower surface as required by claim 30.

Claim 30 further requires a “release button adapted to disengage the latch to release the arm from the slot.” Applicants respectfully disagree with The Examiner’s contention that hinge pins 123 and 124 anticipate the release button of Applicants’ invention. The release button of Applicants’ invention requires the button to disengage the latch to release the arm from the slot. As discussed above, The Examiner asserts Hu discloses a latch 116, which is actually a rail grip 116. The hinge pins 123 and 124 of Hu do not disengage the rail grip 116 to release the arm as required by claim 30, rather the hinge pins 123 and 124 of Hu pivotally attach the rail grip 116 to the mount base 125. Because of this, the hinge pins 123 and 124 themselves cannot disengage the arm as required by claim 30.

Additionally, newly amended independent claim 30 requires “the operator having a threaded shaft, the threaded shaft having a nut thereon, the nut moveable along an axis of the shaft upon rotation of the shaft, the axial movement of the nut against at least one projection rotates the leg about a pivot.” The Examiner further states that Hu discloses a threaded adjustment mechanism 119 which moves the leg and the mount relative to the member. As discussed above, Applicants respectfully submit that Hu refers to “a threaded shaft 119 which extends through mount body 110 (and consequently through transverse bore 131 in central portion 167 of base post 130), clutch member 135 and into interior threads 142 within tightening grip housing 141 of shaft grip 140.” (Col. 19, lines 11-15; Fig. 14). Such a structure is not the same as the threaded shaft of Applicants’ invention. The Examiner also identifies elements 135-137 as a release member that disengages the shaft from the leg. The specification of Hu actually identifies element 135 as a clutch member, and elements 136 and 137 as upper and lower shaft locks respectfully. Such structure is not the same as the threaded shaft and other elements of this claim. As such, Applicants respectfully submit The Examiner has failed to accurately identify such a corresponding structure in Applicants’ invention.

Consequently, the operation of Applicants’ invention as claimed and Hu are clearly different. Hu utilizes a ball and socket joint to achieve desired movement, whereas Applicants’ claimed invention utilizes the interaction of a threaded shaft and a nut with a leg. The Examiner

incorrectly characterizes frustoconical surface 138s and 139 as a nut, which moves along an axis of the shaft upon rotation of the shaft and axial movement of the nut against the projection of the leg. In fact, Hu states that that “relative rotation between frustoconical surface 138 of clutch member 135 and mating frustoconical surface 139 in mount body 110 **is prevented** as clutch member 135 is forced against mount body 110.” (Col. 19, lines 20-24). In contrast, the nut of Applicants’ invention actually facilitates movement, rather than preventing movement. Thus, The Examiner has failed to identify similar frustoconical surfaces 138, 139 in Applicants’ invention. As such, Hu does not disclose each and every element of independent claim 30 as newly amended, thus Hu does not anticipate claim 30. Applicants respectfully assert claim 30 and all dependent claims thereon are patentable as amended.

Applicants further contend Hu fails to disclose “the member having a latch for selectively retaining the clamp at a selected position” and “a leg pivotally connected to the member and extending cantilevered away from the slot at a proximate end of the member” for the same reasons discussed above. As such, Hu does not disclose each and every element of independent claim 30 as newly amended, and thus Hu does not anticipate claim 30. Applicants respectfully assert claim 30 and all dependent claims thereon are patentable as amended.

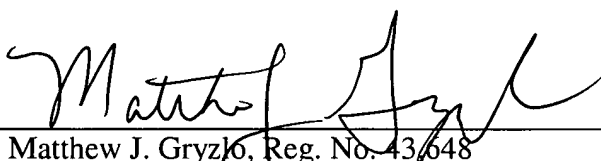
**CONCLUSION**

In light of the foregoing, Applicants respectfully request reconsideration and allowance of claims 17-31. The Commissioner is authorized to charge any additional fees or credit any overpayments associated with this Amendment to Deposit Account 23-0280. Applicants further invite the Examiner to contact the undersigned representative at the telephone number below to discuss any matters pertaining to the present Application.

Respectfully submitted,

Dated: June 27, 2006

By:



Matthew J. Gryzlo, Reg. No. 43,648

Customer No. 23424

Wallenstein & Wagner, Ltd.

311 South Wacker Drive, 53<sup>rd</sup> Floor

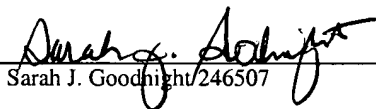
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Sarah J. Goodnight/246507